IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant : David J. Danitz et al.
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Commissioner for Patents
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Appeal Brief under 37 CFR 41.37(c)(1)

This Appeal Brief is submitted in support of the Notice of Appeal which was filed on March 19, 2008. The Examiner has reopened Prosecution After Appeal by initiating a new Non-Final Office Action mailed on February 6, 2009. The applicant would like to continue to Appeal. Please apply the Notice of Appeal of $255 and the Appeal Brief fee of $255 to this Appeal Brief submission. Since the fees have increased from $255 to $270 per submission, the difference of $30 is submitted with this current Appeal Brief.

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(i) ***Real party in interest*** - The real party in interest for this Appeal is the Assignee, Vitalitec International, Inc.

(ii) ***Related appeals and interferences*** - There are no known related interferences and no known related appeals.

(iii) ***Status of claims*** - The claims are as listed in the amendment mailed July 5, 2007 and as set forth in the accompanying Appendix. Thus claims 50-68 are pending in the case, claim 63 is objected to and on appeal and claims 50-62 and 64-68 are rejected and appealed. Claims 1-49 are cancelled.

(iv) ***Status of amendments*** - There were no amendments filed subsequent to the final rejection from which this Appeal is taken.

(v) ***Summary of claimed subject matter*** - The present application is drawn to a surgical instrument, more specifically to the shaft of a surgical clamp and to the structure of the shaft which is well illustrated in Figures 3A and 3B. The shaft is formed of alternating beads which contact each other along lines of contact (LC) defined between convex surfaces of the adjacent beads. This line contact, which is present even when the shaft is bent, minimizes friction between adjacent beads. This results in a shaft which remains very flexible, even when the beads are under compression. This can happen, for example, when the shaft is incorporated into a clamp device. In such a device, when the jaws of the clamp are closed, for example on a blood vessel of a patient, the flexible shaft allows the handle of the device to be bent out of the way. The flexible shaft of the present invention allows this bending to be done with less torque being transmitted to the blood vessel. This is discussed at length in the Specification, for example at page 6, lines 9-26.

The appealed claims include independent claims 50, 56, 61 and 68. Claims 50, 56 and 68 are drawn to a shaft for use with a clamp of the present invention and claim 61 is drawn to the clamp of the present invention.

Claim 50 calls for a shaft for use with a clamp device, comprising the following:

(1) a plurality of alternating first beads and second beads, each of the first and second beads having a surface;

wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second

beads is supported on the surface of two adjacent first beads at a line of contact, and the surface of each of the second beads has a convex shape at the line of contact (FIGS. 3A and 3B, Specification, Page 5, line 17 through Page 6, line 8).

Claim 56 calls for a shaft for use with a clamp device, comprising the following:

(1) a plurality of alternating first beads and second beads, each of the first and second beads having a surface;

wherein each of the second beads is supported on the surface of two adjacent first beads at a line of contact, and the surface of each of the first and second beads has a convex shape at the line of contact (FIGS. 3A and 3B, Specification, Page 5, line 17 through Page 6, line 26).

Claim 61 calls for a clamp, comprising the following:

(1) a handle assembly (FIGS. 1, 2, 4, 5, 6A, 6B and 15, Specification, Page 10, line 9 through Page 12, line 21);

(2) a gripping assembly having a pair of jaws that can be opened and closed to grip an element (FIGS. 9A-9C and 10, Specification, Page 19, line 5 through Page 21, line 19); and

(3) a shaft assembly having:

a flexible shaft having a proximal end that is coupled to the handle assembly and a distal end that is coupled to the gripping assembly (FIGS. 1 and 2, Specification, Page 5, lines 10-17), the flexible shaft defining a bore and comprising a plurality of alternating first beads and second beads, each of the first and second

beads having a surface (FIGS. 2-5, Specification, Page 5, line 10 through Page 6, line 26);

wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second beads is supported on the surface of the two adjacent beads at a line of contact, and each of the second beads has a convex shape at the line of contact (FIGS. 3A and 3B, Specification, Page 5, line 17 through Page 6, line 8); and

(4) a cable which extends through the bore of the flexible shaft (FIG. 3A, Specification, Page 6, lines 9-26), the cable having a proximal end that is operatively coupled to the handle assembly (FIG. 16, Specification, Page 10, lines 16-25) and a distal end that is operatively coupled to the gripping assembly (FIGS. 9A-9C and 10, Specification, Page 20, lines 1-24).

Claim 68 calls for a shaft for use with a clamp device, comprising the following:

(1) a central member (FIG. 7, Specification, Page 7, lines 8-20); and

a plurality of alternating first beads and second beads alternatingly positioned along the central member, wherein the second beads contact adjacent first beads along a line of contact, and wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second beads is supported on a surface of two adjacent first beads at a line of contact, and the surface of each of the second beads has a convex shape at the line of contact (FIGS. 3A and 3B, Specification, Page 5, line 17 through Page 7, line 20).

(vi) ***Grounds of rejection to be reviewed on appeal*** -

There are two (2) grounds of rejection to be reviewed on appeal as follows:

1. The rejection of claims 50-60 and 68 under 35 U.S.C. 103(a) based upon US Patent Number 4,949,927 to Madocks et al. (Madocks) in view of Madocks.

2. The rejection of claims 61, 62, and 64-67 under 35 U.S.C. 103(a) based upon US Patent Number 6,139,563 to Cosgrove, III et al. (Cosgrove) in further view of Madocks.

(vii) *Argument* -

Ground 1

Claims 50-60 and 68 have been improperly rejected under 35 U.S.C. 103(a) over Madocks in view of Madocks.

First of all, in paragraph 4 of the Non-Final Office Action dated February 6, 2009 the Examiner introduces a reference to Tilleman US Patent Number 2,677,901. Tilleman is a patent drawn to an orientation of rosary beads. Tilleman uses cylindrical casings that maybe rolled between the fingers. Figures 1 & 2, Column 3, lines 48-59. These cylindrical casings are cylinders, they do not resemble or obtain the well known shape of a bead. The Tilleman reference is nonanalogous art. After considering Tilleman, a person of ordinary skill in the art would not logically be lead to a clamping device with the alternating convex beads of the present application. Thus the Examiner has not taken the current invention as a whole and has used impermissible hindsight by referencing the extremely nonanalogous art of Tilleman in the Office Action.

Furthermore, in paragraph 2 of the Final Office Action dated September 20, 2007 the Examiner claims that the arguments submitted pertaining to claim 68 in the Amendment dated July 5, 2007 are moot due to a new ground of rejection in the Final Office Action. Since claim 68 is rejected under the same grounds in the Non Final Office Action dated January 5, 2007 as it is in the Final Office Action, this statement by the Examiner in the Final Office

Action is in error. Since claim 68 is rejected under the same grounds in both the Non Final Office Action and the Final Office Action, a new ground of rejection has not been established by the Examiner.

Turning to the existing art rejection of independent claims 50, 56 and 68, there is a clear structural difference between these independent claims and Madocks. Claims 50, 56 and 68 clearly recite "a plurality of alternating first beads and second beads" and clearly state that each of the second beads has a convex shape. Madocks discloses "alternating ball and tubular socket members . . . each has a different bevel angle B as shown in FIG. 1 such that contact angle A is different on each ball member." Madocks, Column 5, lines 37-47. Madocks discloses alternating beveled ball and socket joints not alternating convex shaped beads. Nevertheless, the Examiner contends that Madocks' "alternating ball and tubular socket members" (Madocks, Column 5, lines 37-47), are comparable to the "plurality of alternating first beads and second beads" diagramed in FIGS. 3A and 3B, described on Page 5, line 21 through Page 6, line 8 of the Specification, and recited in independent claims 50, 56 and 68 of the present application.

A socket is defined as "[a]n opening or cavity into which something fits," (The American Heritage Dictionary 785 (Houghton Mifflin Company 4th ed. 2001)); while, beads are defined as small round objects. *Id.* at 76. By definition and simple comparison, one can easily see that the ball and socket configuration of Madocks FIGS. 1 and 2 are not the "plurality of alternating first beads and second beads." The Examiner simply disregards Madocks'

teaching of a ball and socket and substitutes beads without any reference or suggestion as to why a person of ordinary skill in the art would substitute Madocks' ball and socket configuration with the first and second beads of the present application.

In supporting a rejection based upon obviousness the Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). In this instance, the Examiner has replaced Madocks' socket members 10, 14, 16, 18, 20, 22, etc. and ball 12, with the first and second beads 36a and 36b of the present invention without establishing any *prima facie* evidence as to whether one of ordinary skill in the art would perceive Madocks' socket members and ball as interchangeable with the present invention's first and second beads.

The Specification clearly states that:

> [T]he shaft 22 can be made of a plurality of two types of beads 36a and 36b that are alternated with respect to each other. Both types of beads 36a and 36b have a three-dimensional convex torus configuration, which is best shown in FIG. 3B. The first beads 36a have a smaller inner diameter than the second beads 36b. The first beads 36a have an outer diameter that is smaller than, equal to, or greater than, the outer diameter of the second beads 36b. Each second bead 36b rides (i.e., is supported) on the outer

> surface 37a of two adjacent first beads 36a, so that each second bead 36b is essentially in a raised position with respect to the first beads 36a.

Specification, Page 5, lines 22-32. The bead structure of the present application is a unique inventive structure employed to prevent the shaft from becoming rigid when a high axial load is applied to the cable. The smooth surface of the convex torus does not bite into the other bead. If the second bead was a cylinder, such as a socket, the convex torus would create a sharp point on the inside of the cylinder. This sharp point would bite into the subsequent bead under an axial load and cause the flexible shaft to become rigid. The convex torus design of the bead structure of the present application differs from the ball and socket configuration of the prior art because the flexible shaft stays flexible under a high axial load.

Therefore, through manipulation of Madocks, a person of ordinary skill in the art would not be lead to the plurality of alternating convex shaped beads of the present application. Based upon the foregoing, the rejection put forth by the Examiner lacks *prima facie* evidence and does not arrive at the subject matter of claim 50, claim 56 or claim 68, and this rejection is therefore in error and should be reversed.

In addition, the Examiner confirms that Madocks does not disclose that the second bead has a convex shape at the line of contact and that Madocks does not show the second beads have a smaller outer diameter than each of the first beads. However, without providing a *prima facie* case for

obviousness the Examiner asserts that the shape and diameter of the second bead at the line of contact is a matter of design choice. Through a large leap in design choice, the Examiner contends that Madocks' beveled ball and socket configuration may be a convex beaded configuration.

The American Heritage Dictionary defines bevel as "[t]he angle or inclination of a line or surface that meets another at any angle but 90°." The American Heritage Dictionary 84 (Houghton Mifflin Company 4th ed. 2001). Convex is defined as "[c]urved outward, as the exterior of a sphere." *Id.* at 195. Therefore, by definition a beveled edge is a line or surface at any angle but 90°, while a convex shape is an outward curve. A line angle as disclosed by Madocks, such as a beveled edge, does not describe the outward curve, such as a convex shape, of the present application. At the point of contact, the Madocks' socket members have a straight surface, not a convex surface. Madocks, FIGS. 5 and 6.

Independent claims 50, 56 and 68 all call for the second beads to contact the first beads along a line of contact, and for the second beads to have a convex shape at the line of contact (Application, LC in FIG. 3A), while Madocks' socket members have a straight surface at the line of contact. This difference is not a trivial difference, nor is it a matter of obvious design choice. The structures of the present invention are unique because they are intended to maintain flexibility when under compression caused by operation of an internal cable or other member for actuating some function of a surgical instrument. When

under such compression, some deformation of the adjacent surfaces will take place and, invariably, there will be a greater surface area of contact between two components where one has a flat surface, such as Madocks', than there will be between two components where that same component has a convex surface, such as the convex surface of the present application.

Based upon the foregoing, it is respectfully submitted that the rejection of claim 50, claim 56 and claim 68 based upon Madocks has been made in the absence of *prima facie* evidence, and results in an improper hindsight reconstruction of knowledge gleaned from the present disclosure and set forth in the pending claims.

Based upon the foregoing, the rejection of independent claims 50, 56 and 68 are respectfully submitted to be in error, and reversal of this rejection is earnestly solicited.

Dependent claims 51-55 and 57-60 all depend directly or indirectly from independent claims 50 and 56 and are submitted to be patentable based upon this dependency. In addition, each of these claims is submitted to contain patentable subject matter in its own right.

Ground 2

Claims 61, 62 and 64-67 have been improperly rejected under 35 U.S.C. 103(a) over Cosgrove in further view of Madocks.

Turning to the existing art rejection of independent claim 61, there is a clear structural difference between this independent claim and the combination of Cosgrove and Madocks.

Refering to the application, lines 9-10 of claim 61 clearly recite "a plurality of alternating first beads and second beads" and lines 15-16, of claim 61 clearly state that "each of the second beads has a convex shape." Cosgrove discloses "a series of interconnected ball and socket segments 38." Cosgrove, FIGS. 7d-7e, Column 5, lines 46-59. Cosgrove discloses interconnected ball and socket joints not alternating convex shaped beads. Nevertheless, the Examiner contends that Cosgrove's interconnected ball and socket joints are comparable to the "plurality of alternating first beads and second beads" diagramed in FIGS. 3A and 3B of the present application.

As discussed in Ground 1, a socket is defined as "[a]n opening or cavity into which something fits," (The American Heritage Dictionary 785 (Houghton Mifflin Company 4th ed. 2001)) while beads are defined as small round objects. *Id.* at 76. By definition and simple comparison, one can easily see that the ball and socket configuration of Cosgroves FIGS. 7d and 7e are not the same as the "plurality of alternating first beads and second beads" diagramed in FIGS. 3A and 3B of the present application and recited in lines 9-10 of claim 61. The Examiner simply disregards Cosgrove's teaching of a ball and socket and substitutes beads without any reference or suggestion as to why a person of ordinary skill in the art would regard Cosgrove's

ball and socket configuration as comparable to or the same as the first and second beads of the present application.

In supporting a rejection based upon obviousness the Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). In this instance, the Examiner has replaced Cosgrove's ball and socket configuration 38, with the first and second beads 36a and 36b of the present application without establishing any *prima facie* evidence as to whether one of ordinary skill in the art would perceive Cosgrove's ball and socket configuration as interchangeable with the present applications first and second beads.

As stated in Ground 1, the bead structure of the present application is a unique inventive structure employed to prevent the shaft from becoming rigid when a high axial load is applied to the cable. The smooth surface of the convex torus does not bite into the other bead. If the second bead was a cylinder, such as a socket, the convex torus would create a sharp point on the inside of the cylinder. This sharp point would bite into the subsequent bead under an axial load and cause the flexible shaft to become rigid. The convex torus design of the bead structure of the present application differs from the ball and socket configuration of the prior art because the flexible shaft stays flexible under a high axial load.

Based upon the foregoing, the rejection put forth by the Examiner lacks *prima facie* evidence and does not arrive at the subject matter of claim 61, and this rejection is therefore in error and should be reversed.

In addition, line 16 of claim 61 clearly calls for the structure of the second beads as "a convex shape at the line of contact," which is absent from both Cosgrove and Madocks. Cosgrove and Madocks make no mention of beads, and neither mention second beads that contact the first beads along a line of contact, for the second beads to have a convex shape at the line of contact, and that the second beads have a larger inner diameter than each of the first beads. The Examiner concedes that base reference Cosgrove as applied to claim 61 makes no mention of these structures; however, the Examiner relies upon Madocks and obvious design choice for the teaching of these structures. As stated in Ground 1 above, Madocks fails in this regard and a large leap in design choice is taken.

In paragraph 13, lines 4-5 of the Office Action dated September 20, 2007 and in paragraph 10, lines 9-10 of the Office Action dated February 6, 2009, the Examiner confirms that "Madocks does not specifically disclose the bevel surface of the socket or second beads is a convex surface." However without providing a *prima facie* case for obviousness that Madock's and Cosgrove's ball and socket configurations may be the beaded configuration of the present disclosure, the Examiner asserts, even though neither references disclose any structured bead, that the shape of the second bead at the line of contact is a matter of design choice. Through a large leap in design choice,

the Examiner contends that Madocks' beveled ball and socket configuration may be a convex beaded configuration.

As discussed in Ground 1, a line angle as disclosed by Madocks, such as a beveled edge, does not describe an outward curve, such as a convex shape, of the present application. At the point of contact, the Madocks and Cosgrove ball and socket configurations have a straight surface, not a convex surface. Madocks, FIGS. 5 and 6; Cosgrove, FIGS. 7d and 7e.

Independent claim 61 calls for the second beads to contact the first beads along a line of contact, and for the second beads to have a convex shape at the line of contact (Application, LC in FIG. 3A), while Madocks' socket members and Cosgrove's ball and socket have straight surfaces at the line of contact. This difference is not a trivial difference, nor is it a matter of an obvious design choice. The structures of the present invention are unique because they are intended to maintain flexibility when under compression caused by operation of an internal cable or other member for actuating some function of a surgical instrument. When under such compression, some deformation of the adjacent surfaces will take place and, invariably, there will be a greater surface area of contact between two components where one has a flat surface, such as Cosgrove's and Madocks', than there will be between two components where that same component has a convex surface, such as the convex surface of the present application.

Based upon the foregoing, it is respectfully submitted that the rejection of claim 61 based upon the combination

of Cosgrove and Madocks has been made in the absence of *prima facie* evidence, and results in an improper hindsight reconstruction of knowledge gleaned from the present disclosure and set forth in the pending claims.

Based upon the foregoing, the rejection of independent claim 61 is respectfully submitted to be in error, and reversal of this rejection is earnestly solicited.

Dependent claims 62 and 64-67 all depend directly or indirectly from independent claim 61 and are submitted to be patentable based upon this dependency. In addition, each of these claims is submitted to contain patentable subject matter in its own right.

Conclusion

This application has been in active prosecution with the Examiner since November 30, 2005. After conducting a personal interview on February 9, 2006, responding to a Final Office Action dated May 11, 2006 where the Examiner enlarges a prior art figure to argue that structures are present which are not actually shown in the prior art, filing a Request for Continued Examination, responding to a subsequent Non Final Office Action dated January 5, 2007 establishing a new ground of rejection for all of the claims in the present application, filing a Appeal Brief on September 18, 2008, and the filing of this subsequent Appeal Brief in response to a Non Final Office Action reopening prosecution, it is submitted that an earnest and thorough effort has been made by the undersigned to resolve

the outstanding issues in this case and place the same in condition for allowance.

The application contains four independent claims. Each of these claims as set forth above clearly contain allowable subject matter. Claim 63 has been indicated as allowable and is currently objected to due to its dependency upon a rejected base claim. Claims 50-62 and 64-68 have been rejected, and it is respectfully submitted that these rejections are in error.

Reversal of the rejection of these claims is therefore earnestly solicited.

Please apply the Notice of Appeal fee of $255 and the Appeal Brief fee of $255 to this Appeal Brief submission. Since the fees have increased from $255 to $270 per submission, the difference of $30 is submitted with this current Appeal Brief. Please charge any other fee or fee deficiency that may be due to Deposit Account 02-0184.

Respectfully submitted,

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Claims Appendix

Listing of Claims:

1-49. (Canceled)

50. (Rejected and on Appeal) A shaft for use with a clamp device, comprising:

a plurality of alternating first beads and second beads, each of the first and second beads having a surface;

wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second beads is supported on the surface of two adjacent first beads at a line of contact, and the surface of each of the second beads has a convex shape at the line of contact.

51. (Rejected and on Appeal) The shaft of claim 50, wherein the surface of each of the first beads has a convex shape at the line of contact.

52. (Rejected and on Appeal) The shaft of claim 50, wherein each of the second beads has a larger outer diameter than each of the first beads.

53. (Rejected and on Appeal) The shaft of claim 50, wherein each of the second beads has a smaller outer diameter than each of the first beads.

54. (Rejected and on Appeal) The shaft of claim 50, wherein each of the second beads has the same outer diameter as each of the first beads.

55. (Rejected and on Appeal) The shaft of claim 50, wherein the line of contact is a circular line of contact.

56. (Rejected and on Appeal) A shaft for use with a clamp device, comprising:

a plurality of alternating first beads and second beads, each of the first and second beads having a surface;

wherein each of the second beads is supported on the surface of two adjacent first beads at a line of contact, and the surface of each of the first and second beads has a convex shape at the line of contact.

57. (Rejected and on Appeal) The shaft of claim 56, wherein each of the second beads has a larger outer diameter than each of the first beads.

58. (Rejected and on Appeal) The shaft of claim 56, wherein each of the second beads has a smaller outer diameter than each of the first beads.

59. (Rejected and on Appeal) The shaft of claim 56, wherein each of the second beads has the same outer diameter as each of the first beads.

60. (Rejected and on Appeal) The shaft of claim 56, wherein the line of contact is a circular line of contact.

61. (Rejected and on Appeal) A clamp, comprising:

a handle assembly;

a gripping assembly having a pair of jaws that can be opened and closed to grip an element; and

a shaft assembly having:

a flexible shaft having a proximal end that is coupled to the handle assembly and a distal end that is coupled to the gripping assembly, the flexible shaft defining a bore and comprising a plurality of alternating first beads and second beads, each of the first and second beads having a surface;

wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second beads is supported on the surface of the two adjacent beads at a line of contact, and each of the second beads has a convex shape at the line of contact; and

a cable which extends through the bore of the flexible shaft, the cable having a proximal end that is operatively coupled to the handle assembly and a distal end that is operatively coupled to the gripping assembly.

62. (Rejected and on Appeal) The clamp of claim 61, wherein the surface of each of the first beads has a convex shape at the line of contact.

63. (Objected to and on Appeal) The clamp of claim 61, further including a rigid element that can be placed at a first position where the rigid element supports the shaft in a manner where the shaft cannot be bent, and in a second position where the shaft can be bent.

64. (Rejected and on Appeal) The clamp of claim 61, wherein each of the second beads has a larger outer diameter than each of the first beads.

65. (Rejected and on Appeal) The clamp of claim 61, wherein each of the second beads has a smaller outer diameter than each of the first beads.

66. (Rejected and on Appeal) The clamp of claim 61, wherein each of the second beads has the same outer diameter as each of the first beads.

67. (Rejected and on Appeal) The clamp of claim 61, wherein the line of contact is a circular line of contact.

68. (Rejected and on Appeal) A shaft for use with a clamp device, comprising:

a central member; and

a plurality of alternating first beads and second beads alternatingly positioned along the central member, wherein the second beads contact adjacent first beads along a line of contact, and wherein each of the second beads has a larger inner diameter than each of the first beads, each of the second beads is supported on a surface of two adjacent first beads at a line of contact, and the surface of each of the second beads has a convex shape at the line of contact.

Evidence Appendix

None

Related Proceedings Appendix

None